
From: Clorinda Walley [cwalley@cdfund.org]
Sent: Wednesday, December 19, 2012 11:50:16 PM
To: William Daniels
CC: Mike Banigan
Subject: AMD Fund
Attachments: image001.gif; Regeneron Projections 2013_121912.xlsx;
Regeneron_AMD_Agrmnt_Signed_112311_cw.pdf

Hi Bil,

As discussed, Chronic Disease Fund is committed to being effective and efficient with every dollar donated to us. We solicit funds based upon projected need as determined by historical utilization and projected growth. The AMD program has a very high utilization rate and without adequate funding Chronic Disease Fund will run out of funding for new patients. As you are aware, we fund our renewal patients first then new patients in accordance with the first come, first served requirement.

Regeneron's commitment to donate \$2.5 million in January is very generous and very much appreciated. However, these dollars are not sufficient to keep the program open through January. Mike and I would be happy to meet with your internal team to review and discuss the projections as soon as you are available.

Once again, Chronic Disease Fund appreciates your partnership and looks forward to the opportunity to further discuss this with you.

Kindest Regards,

Clorinda

Clorinda Walley
Executive Director

(972) 608-7163 Direct
(214) 498-8504 Mobile
www.cdfund.org

Chronic Disease Fund 

CDF DTPA 2012 91%

AMD Cancellation Rate 20%

Projected Growth Rate by Disease

AMD 0%

Total New Patient Funding Needed \$ 15,032,967

Total Existing \$ 9,810,989

Total Projected Funding Needed \$ 24,843,956

	Projected New Patients by Quarter 2013				
	1st	2nd	3rd	4th	
<u>Age Related Macular Degeneration Patients</u>	2,500	2,500	2,400	2,100	
AMD 1 -Projected Funding Per Patient	\$ 1,800	\$ 1,800	\$ 1,800	\$ 1,800	
AMD 2 -Projected Funding Per Patient	\$ 1,800	\$ 1,800	\$ 1,800	\$ 1,800	
Projected Funding By Quarter	\$ 4,945,055	\$ 4,945,055	\$ 4,747,253	\$ 4,153,846	
Cancellation	\$ 989,011	\$ 989,011	\$ 949,451	\$ 830,769	
Projected Funding Needed By Quarter	\$ 3,956,044	\$ 3,956,044	\$ 3,797,802	\$ 3,323,077	
Projected CY Funding	\$ 18,791,209				
Projected CY Funding Minus Cancellations	\$ 15,032,967				

Rollover Patients Estimated Renewals	
<u>Age Related Macular Degeneration Patients</u>	6,200
AMD 1 -Projected Funding Per Patient	\$ 1,800
AMD 2 -Projected Funding Per Patient	\$ 1,800
Projected Funding Needed	\$ 12,263,736
Cancellation	\$ 2,452,747
Projected Renewal Funding	\$ 12,263,736
Projected CY Funding Minus Cancellations	\$ 9,810,989

DONATION AGREEMENT

THIS DONATION AGREEMENT (this "Agreement") is made and entered into as of November 18, 2011 (the "Effective Date"), by and between Chronic Disease Fund, Inc., a non-profit corporation and Regeneron Pharmaceuticals, Inc., a New York corporation.

1. **Recitals.** Chronic Disease Fund, Inc. (the "Foundation") is a charitable, non-profit 501(c)(3) public charity, located at 6900 Dallas North Parkway, Suite 200, Plano, TX 75024 formed for the purpose of providing financial support for underinsured patients with certain medical conditions. The Foundation has an assistance program for patients being treated for Age-Related Macular Degeneration ("AMD") with any medically appropriate therapy who meet certain financial and medical criteria ("Program"), which may include assistance paying or reimbursing such patients' deductibles, co-payments and co-insurance. Regeneron Pharmaceuticals, Inc., (the "Donor") desires to provide the Foundation with a donation for the Program.

directly influenced or controlled by any manufacturer or any of its affiliates (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager) who donates to the Foundation, including but not limited to the Donor. Donor will not be the sole pharmaceutical manufacturer solicited for funding of the Foundation or the Program.
2. **Non-Profit Status of Foundation.** The Internal Revenue Service ("IRS") recognizes the Foundation as a federal tax-exempt section 501(c)(3) organization; therefore, any donations received by the Foundation, including those made pursuant to this Agreement, will be tax-deductible to the fullest extent allowed by law. Within thirty (30) days of the Donation, as defined in Section 4, provided to the Foundation, the Foundation will provide a copy of the Foundation's exemption determination letter from the IRS to Donor, as well as, a letter that attests to the existence of the Donation and that Donor may use such letter for its valid purposes.
3. **Independence of the Foundation and Program.**
 - (a) The Foundation will be governed by an independent Board of Directors (the "Board"). Administration and operation of the Foundation and Program will be at the sole discretion of the Board. The Board will have complete authority regarding the distribution of all Program funds (including the Donation). Program administration, operation, and allocation of funds will comport with the Foundation's charitable purpose, applicable local state and federal laws, rules and regulations, and the policies adopted by the Board. Specifically, the make-up and governance of the Board and the Foundation shall be as a *bona fide*, independent charity as described by the Office of the Inspector General in the November 2005 Special Advisory Bulletin titled "Patient Assistance Programs for Medicare Part D Enrollees" unaffiliated with the Donor as well as any other pharmaceutical manufacturer who donates to the Foundation. Further, the Foundation has received a favorable OIG opinion that supports the "Program" as documented in OIG Opinion 06-10
 - (b) Donor will not have any representative on the Board (or participate or otherwise observe any Board meeting), nor will Donor have any input regarding selection of the Foundation's directors or officers. Further, Foundation and its Board shall not be formed, nor indirectly or
4. **Donation.**
 - (c) Program eligibility criteria will be developed by the Board without consideration or input by Donor. A copy of the Program eligibility criteria shall be provided to Donor during the term of this Agreement. Donor will have no control or participation in determinations affecting distributions of Program funds to providers, suppliers, or patients, the providers or suppliers used by patients, or the products or treatments provided to patients to treat or in connection with AMD. The Donation shall not be attributed to the Donor by the Foundation or the Board, except as required by applicable IRS Regulations or other applicable Laws.
 - (d) Lastly, the criteria established by the Board and the Foundation shall be based on a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. Some of the factors that will be considered will be: local cost of living, a patient's assets and expenses, a patient's family size, and the scope and extent of a patient's medical bills.
5. **Donation.**
 - (a) Donor shall endeavor to provide the Foundation with funding to support the Foundation's mission of providing deductible, co-payment and co-insurance assistance (and/or such other forms of assistance as may be determined by the Foundation) to patients meeting the Program's objective financial eligibility criteria, so that such patients may obtain prescription drug (or biologic) therapy for or in connection with AMD during the Term (as defined in Section 7(a) below) (the "Donation").
 - (b) Subject to Section 7(f), Donor shall provide the Foundation with funding in the amount of five hundred thousand dollars (\$500,000), payable in quarterly installments with the first payment due within thirty (30) days of the launch of its product for AMD, anticipated in November 2011 ("Initial Donation").
 - (c) If Foundation determines that the Initial Donation does not meet the needs of the patients who seek assistance from the Foundation for AMD during the Term, Foundation shall notify the Donor in writing but no less than sixty (60) days before the Initial Donation has been depleted. Both parties shall meet to discuss the potential for an additional donation and for what amount. If both Parties mutually agree to an additional

donation during the Term, the Parties shall execute an addendum that provides the terms and conditions of such additional donation (an "Addendum"). A sample Addendum is provided as Exhibit A.

- (d) If Donor desires to provide additional donations to the Foundation, Donor shall notify the Foundation in writing of the contemplated donation amount, and both Parties shall discuss the contemplated donation amount and shall execute an Addendum for such amount.
- (e) The Parties acknowledge and agree that the Donation does not represent a fee for any services rendered by the Foundation to Donor.
- (f) Donor shall pay the Initial Donation and any additional donation amounts via wire transfer. Foundation's wire transfer information is as follows:

JP Morgan Chase, NA
500 Stanton Christina Road
Newark, DE 19713
Account#: 877205302
ABA# for Checks and ACH: 111-000-614
ABA# for Wires: 021-00-0021

5. Use of Donation.

- (a) The Foundation will use the Donation for purposes of administering the Program and providing financial assistance to eligible patients who are receiving therapy for treatment of AMD as determined by the criteria established by the Board of the Foundation. For an amount that shall not exceed ten percent (10%) of the Donation, Foundation may pay for operation and capital expenditures of the Foundation as determined by the Board to be necessary to operate the Program (collectively, "Administrative Expenses"). Examples of Administrative Expenses include, but are not limited to, the following:
 - costs and fees associated with: outside consultants, auditors and auditing or legal counsel providing services on behalf of the Foundation, e.g., costs incurred by the Foundation in connection with a Program Audit
 - premiums for customary insurance purchased on behalf of the Foundation, its officers and directors;
 - Foundation start-up and development costs, reasonable travel expenses and honoraria paid in connection with Board meetings; and
 - payment for informational materials concerning the Foundation and the Program, including costs associated with a therapy management program.
- Any payments made pursuant to this Section 5(a) shall be reasonable and necessary for the operation of the Program and shall be in an amount that is not in excess of fair market value.
- (b) In operating the Program, the Foundation will not discriminate against or otherwise vary its procedures for processing a patient who applies to the Program based upon the treatment prescribed for such patient,

specifically Foundation shall not preferentially treat or discriminate against a patient whose treatment is manufactured or marketed by Donor or upon any physician or supplier utilized by such patient.

- (c) Nothing in this Agreement will prohibit the Foundation from collecting additional funds ("Additional Funding") from sources other than Donor for this Program or other programs being operated by the Foundation, and nothing in this Agreement will restrict the Foundation's discretion with respect to the use of such Additional Funding consistent with its charitable purpose and the policies adopted by the Board from time to time during the term of the Agreement.

6. Representations and Warranties.

- (a) Subject to applicable requirements that may be imposed by the IRS in connection with the Foundation obtaining tax-exempt status as a 501(c)(3) organization, each Party represents that (i) such Party is a corporation duly organized, validly existing and in good standing under the laws of its respective jurisdiction of incorporation; (ii) this Agreement constitutes a valid and binding obligation of such Party enforceable in accordance with its terms, except as limited by applicable bankruptcy, insolvency, reorganization, moratorium, and similar laws affecting the enforcement of creditors' rights generally and the application of general principles of equity and judicial discretion; and (iii) neither the execution and delivery of this Agreement nor the performance hereunder (A) constitutes a violation of, default under, or conflicts with any agreement or instrument to which such Party is bound, terms of the articles of incorporation, bylaws or other organizational documents of such Party, or any provision of applicable law, regulation or published interpretive guidance or ruling to which such Party is bound or (B) requires any consent or other action by or filing with any third party or governmental body or agency to which such Party is bound.
- (b) The Foundation represents and warrants that the Program (including any third parties retained by the Foundation to perform services under the Program, e.g., agents, contractors, consultants) will comply with the provisions of all applicable laws, statutes, rules and regulations, as amended from time to time, including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) or the corresponding provision of any future United States law (the "Anti-Kickback Statute"), and the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a(a)(5) or the corresponding provision of any future United States law (the "Civil Monetary Penalties Law"). The practices, procedures and forms the Foundation will use to administer the Program will be consistent in all material respects with the policies expressed by the Office of Inspector General ("OIG") of the United States Department of Health and Human Services, including but not limited to the November 2005 Special Advisory Bulletin titled "Patient Assistance Programs for Medicare Part D Enrollees". The Foundation further agrees to notify Donor in writing within fifteen (15) days of being informed by any governmental or regulatory authority that any of its material practices, procedures or forms no longer

satisfies any of the requirements described herein. Within thirty (30) days of the Foundation sending such written notification to Donor, the parties may (i) discuss alterations to the Program and/or this Agreement that would bring all material practices, procedures or forms into compliance with the requirements described herein; or (ii) upon written notification by either party, terminate the Agreement. If, within thirty (30) days of the Foundation sending written notification to Donor, the parties have not agreed, in writing, to alterations to the Program and/or this Agreement that both parties agree cure all material practices, procedures, or forms deemed non-compliant by a governmental or regulatory authority, this Agreement will terminate immediately.

- (c) Donor represents and warrants that its support of, and Foundation represents and warrants that its use of the Donation for purposes of the Program complies with all applicable laws, statutes, rules and regulations, as amended from time to time, including, but not limited to, the Anti-Kickback Statute, the Civil Monetary Penalties Law, and the policies of the OIG.

7. Term and Termination.

- (a) The term of this Agreement will commence on the Effective Date and will continue for a period of one year (the "Term"), and the Parties have the option to renew for additional consecutive terms of one (1) year each (each a "Renewal Term"), unless earlier terminated in accordance with the terms hereof. To effectuate each Renewal Term, each Party must execute an amendment to this Agreement that establishes the Donation and terms for said Renewal Term.
- (b) Upon not less than ninety (90) days advance written notice to the other Party, a Party may terminate this Agreement for any reason.
- (c) This Agreement may be terminated by a Party at any time in the event the other Party materially breaches this Agreement. In such event, the non-breaching Party will notify the Party in breach of such breach in writing. The Party in breach will have thirty (30) days from the date of its receipt of such notice to cure such breach ("Cure Period"). If, at the conclusion of the Cure Period, the Party in breach has failed to cure the breach, the non-breaching Party may immediately terminate the Agreement.
- (d) Each Party will have the right to terminate this Agreement upon not less than ninety (90) days' prior written notice in the event that any federal, state or local statute, law, legislation, regulation, rule guidance, order or other pronouncement from a court or governmental authority (collectively, "Law") is promulgated, issued or enacted, or a change or interpretation of an existing Law is promulgated, issued or made, which in the opinion of the Party giving such notice could result in this Agreement, or any performance hereunder, being found to violate applicable law or would otherwise have a material adverse effect on such Party and/or any of its affiliates if this Agreement remains in effect. During the 90-day period prior to termination, the Parties will in good faith discuss alterations to the Program and/or this

Agreement that would bring it into compliance with applicable Law.

- (e) Upon the termination or expiration of this Agreement for any reason, each Party will promptly return to the other Party all Confidential Information that is owned or was provided by the other Party (as such term is defined in Section 12 below).
- (f) Donor may terminate this Agreement upon written notice to Foundation if the launch of its product for AMD does not occur prior to December 31, 2011.
- (g) In addition, upon termination of this Agreement by Donor pursuant to Section 6(b), 7(c) or 7(d) or Foundation pursuant to Section 6(b), 7(b) or 7(d), if the Donation has not been depleted at such time, the parties shall meet to determine how any unused portion of the Donation shall be allocated, e.g., either among other similar programs administered by the Foundation or by forwarding such portion to another charitable organization designated by the Donor, and Foundation shall take into consideration Donor's choice, provided that it is consistent with the Foundation's charitable mission.

8. Administration of the Program. The Foundation may desire to engage third parties who shall perform services that are necessary to the Program, e.g., an independent consulting organization, for the purpose of providing certain administrative and management services to the Foundation in connection with the operation of the Program. Such third parties will perform their duties in a manner that does not conflict with any terms and conditions of this Agreement. To ensure the confidentiality of the Donors' Confidential Information, the Foundation shall enter into a written agreement with such third parties to protect such Confidential Information that is owned or was provided by the Donor to Foundation.

9. Recordkeeping and Audits.

- (a) The Foundation agrees to maintain accurate and complete records of all contracts, papers, correspondence, copybooks, accounts, invoices and other information in the Foundation's possession relating to the Program.
- (b) The Foundation agrees to undergo an independent annual audit of the Program ("Program Audit") consistent with the parameters set forth in Exhibit B. Any costs incurred by the Foundation in connection with the Program Audit will be paid from the Program's operational funding and will be considered Administrative Expenses for purposes of Section 5(a) of this Agreement.
- (c) The Foundation agrees to undergo an audit by the Donor based on a reasonable basis by the Donor with respect to the Foundation's compliance with the terms and conditions of this Agreement (the "Donor Audit"). Donor shall describe in writing the basis of Donor's desire for such audit as well as requested timeframe to complete such audit. Within thirty (30) days of the Foundation's receipt of such written description, the Parties shall meet to determine the appropriate

schedule and parameters of such Donor Audit. Donor shall hire an independent third party to conduct such audit who shall comply with all applicable laws, rules and regulations with respect to the receipt of the Foundation's information, e.g., HIPAA and state privacy laws. The findings of such Donor Audit shall be shared with the Foundation and the Board.

10. Publicity of Foundation; Advertising.

- (a) Subject to the provisions of Section 10(b) or (c), the Foundation will use commercially reasonable efforts to ensure that appropriate physicians, suppliers, patient advocacy groups and other relevant third party organizations are informed about the availability of the Program and its potential benefits for patients suffering from AMD. The Foundation may also use commercially reasonable efforts to publicize the availability of the Program directly to patients who may be eligible for assistance under the Program.
- (b) Unless otherwise required by applicable Law or approved, in advance, in writing by Donor in response to Foundation's written request, the Foundation will not disclose to the public, media or any other third party the Donor's contribution and relationship with the Foundation, nor shall the Foundation communicate to third parties regarding Donor's products or identify Donor's products in public statements unless such communication or identification of Donor's products occurs such that the Foundation (i) discusses the products as part of a general description of the Foundation's activities, (ii) lists Donor's products as one of many products that are supported by the Foundation, and (iii) does not show preference or bias to Donor's products.
- (c) Donor will not advertise or otherwise disclose to the public its financial support for the Program except as may be required by any court order or applicable Law.

11. Data Collection and Reporting.

- (a) The Foundation will own all data that it collects pursuant to the Program. The Foundation will hold confidential all data that are individually identifiable or product-specific in compliance with applicable Law, specifically HIPAA and relevant state privacy laws, rules and regulations. However, the Foundation may use the data it collects to prepare aggregate data and analyses, which it may disclose to Donor and other third parties, consistent with the applicable guidelines, e.g., cannot facilitate the Donor in correlating the amount or frequency of its Donations with the number of subsidized prescriptions for its products
- (b) The Foundation will submit monthly reports (the "Monthly Reports") relating to the Program to Donor within fifteen (15) days after the end of each calendar month, unless Donor otherwise agrees to a less frequent reporting period. Monthly Reports will contain only aggregate numbers of all applicants or clients according to classification of disease category. Monthly Reports will not include any information specific to a particular product or particular provider or supplier or any individually identifiable health information (as such

term is defined at 45 CFR § 164.103). Each Monthly Report will include the following elements:

- (i) Number of applications received for the Program;
- (ii) Number of applicants accepted for the Program;
- (iii) Number of applicants for the Program denied and reason(s) for denial;
- (iv) Average amount paid to recipients in the Program for cost sharing obligations (e.g., co-payment, co-insurance);
- (v) Total amount paid out by the Program (by month and year-to-date);
- (vi) Total amount allocated to enrolled patients in the Program but not yet paid out.

Subject to notice provision in Section 4(a), as part of the Monthly Reports, the Foundation will track and report to Donor how much of Donor's Donation remains available for use in the Program, as determined by objective criteria utilized by the Foundation. The Foundation may provide additional information in each Monthly Report as approved by the Board and the Foundation's legal counsel.

12. Confidentiality. Donor and the Foundation acknowledge that each Party may have access to certain Confidential Information (as defined below) of the other Party. In consideration of any disclosure or release of Confidential Information by each Party, Donor and the Foundation hereby agree as follows:

- (a) "Confidential Information" means all technical, scientific, trade, research, manufacturing, marketing, commercial, supplier, operational, administrative, corporate, financial and other proprietary information of any kind whatsoever furnished by one Party (the "Disclosing Party") to the other (the "Receiving Party"), whether in writing or orally. Confidential Information will be treated as the proprietary, confidential and trade secret information of the Disclosing Party and will not be disclosed by the Receiving Party to any other party or used by the Receiving Party in any manner whatsoever other than for carrying out its obligations set forth in this Agreement. Confidential Information does not include: (i) information that is or becomes in the public domain (provided that such information did not enter the public domain as a result of the Receiving Party's, or its employee's or agent's, breach of this Agreement); (ii) information that was disclosed to the Receiving Party by a third party without an obligation of confidentiality and having a legal right to make such disclosure; (iii) information that is approved for public release by the prior written authorization of the Disclosing Party; (iv) information that the Receiving Party can establish was independently developed (as evidenced by competent written documentation) and was not acquired, directly or indirectly from the Disclosing Party without breaching this Agreement; or (v) information which at the time of disclosure to the Receiving Party was known to the Receiving Party free of restriction (as evidenced by competent written documentation).

- (b) The Receiving Party will (i) hold and maintain in confidence all Confidential Information, (ii) not use any Confidential Information for any purpose other than for carrying out its obligations set forth in this Agreement or as otherwise agreed in writing by the Disclosing Party and (iii) not disclose any Confidential Information to any person or entity other than to those directors, officers, partners, managers, members, employees, representatives, agents and advisors (and those of its subsidiaries and affiliates) (collectively, "Agents") of the Receiving Party who need to know the Confidential Information for purposes of the Program and who will be advised by the Receiving Party of the terms of this Agreement and who will be bound by restrictions similar to those set forth herein regarding disclosure and use of such Confidential Information. The Receiving Party will be responsible for the breach of any of the terms hereof by any Agent to whom the Receiving Party discloses any Confidential Information.
- (c) Each Party's obligations set forth in this Section 12 will remain in full force and effect during the term of this Agreement and for five (5) years after termination thereof.
- (d) At any time upon the request of the Disclosing Party or upon the expiration or termination of this Agreement, the Receiving Party agrees to return to the Disclosing Party all Confidential Information in its possession, including without limitation, all paperwork, reports and program financial records, excluding patient names and other individually identifiable health information (as such term is defined at 45 CFR § 164.103); *provided, however*, that the Receiving Party may retain a copy of such Confidential Information for its confidential legal record keeping purposes.
- (e) In the event that the Receiving Party is requested or required (pursuant to an applicable Law or by a subpoena, civil investigative demand or other process) to disclose any Confidential Information, the Receiving Party will provide the Disclosing Party with prompt notice of any such request or requirement; *provided*, that the Receiving Party (i) promptly notifies the Disclosing Party in writing of the existence, terms and circumstances of such required disclosure, (ii) consults with the Disclosing Party on the advisability of taking legally available steps to resist or narrow such disclosure and (iii) takes all reasonable and lawful actions to help enable the Disclosing Party to obtain confidential treatment for such disclosure.
- (f) Nothing contained in this Agreement will be deemed (i) to be a license to the Receiving Party of any patent rights, trade secret rights or know-how rights related to Confidential Information or (ii) to create any obligation of the Disclosing Party to disclose any Confidential Information.
- (g) The Parties acknowledge the restrictions contained in this Section 12 are reasonable and necessary to protect the legitimate business interests of the Parties and that any violation of any provisions hereof may result in irreparable injury to the Parties and the clients and patients each such Party services. Each Party also

acknowledges that the other Party may be entitled to temporary and permanent injunctive relief if any violation of any provision occurs.

- (h) The Receiving Party will indemnify the Disclosing Party for any breach of the Receiving Party's confidentiality obligation hereunder.

13. Proprietary Rights. Each Party reserves the right to control the use of its names and all symbols, trademarks or service marks presently existing or later established. Neither Party will use the other Party's name, symbols, trademarks or service marks in advertising or promotional materials or otherwise, except with the prior written consent of such Party; provided that Donor may disclose the name and contact information of the Foundation in connection with listing or referring parties to independent non-profit organizations that support AMD.

14. Indemnification.

- (a) The Foundation will indemnify and hold harmless Donor and Donor's stockholders, officers, directors, employees, agents, representatives and affiliates for any loss, liability, claim, damage (including incidental and consequential damages) or expense (including costs of investigation and defense and reasonable attorneys' fees) (collectively, "Claims") arising from (i) the gross negligence or willful misconduct of the Foundation or its representatives or agents with respect to this Agreement or (ii) the breach by Foundation of any obligations, and representation or warranties under this Agreement, except to the extent that the loss, liability, claim, damage or expense arose from the gross negligence or willful misconduct of Donor.
- (b) Donor will indemnify and hold harmless the Foundation and the Foundation's directors, officers, employees, agents, representatives and affiliates for any Claims arising from (i) the gross negligence or willful misconduct of Donor or its employees or agents with respect to this Agreement or (ii) the breach by Donor of any obligations and representation or warranties under this Agreement except to the extent that the loss, liability, claim, damage or expense arose from the gross negligence or willful misconduct of the Foundation.
- (c) In the event of a Claim, the indemnification procedures will be as follows:
 - (i) Promptly after receipt by any indemnified Party of notice of the assertion of any Claim, the indemnified Party will give written notice thereof to the indemnifying Party and will thereafter keep the indemnifying Party reasonably informed with respect thereto; *provided*, that failure to give the indemnifying Party prompt notice as provided in this Section 14 will not relieve the indemnifying Party of its obligations hereunder except to the extent, if any, that they will have been prejudiced thereby.
 - (ii) In case any such Claim is brought against any indemnified Party, the indemnifying Party will be entitled to participate in (and, if they will wish, to assume) the defense thereof with counsel

reasonably satisfactory to the indemnified Party. If the indemnifying Party assumes the defense of any claim or litigation as provided in this subsection, the indemnified Party will provide reasonable assistance to the indemnifying Party in its efforts to investigate and defend the Claim, including, without limitation, providing reasonable access by the indemnifying Party to such documentary evidence and witnesses as are available to the indemnified Party. If the indemnifying Party assumes the defense of any Claim provided in this subsection, the indemnifying Party will, subject to subsection (iv) below, have the authority to settle or compromise the Claim. No compromise or settlement of a Claim by the indemnified Party will be binding on the indemnifying Party without the consent of the indemnifying Party.

(iii) If the indemnifying Party fails to assume the defense of such Claim within thirty (30) days after notice of such Claim or such shorter period of time as is necessary to avoid adversely affecting the defense of such Claim, the indemnified Party against whom such Claim has been made will have the right (upon further notice to the indemnifying Party) to undertake the defense, compromise and settlement of such claim on behalf of and for the account and risk, and at the expense of, the indemnifying Party, subject to the right of the indemnifying Party to assume the defense of such Claim at any time prior to settlement, compromise or final determination thereof.

(iv) Notwithstanding anything in this Section 14 to the contrary, neither Party will, without the written consent of the other Party (a) settle or compromise any Claim in any manner that includes an admission of fault or liability on the part of the other Party; or (b) settle or compromise any Claim in any manner that may adversely affect the other Party other than as a result of monetary damages or other money payments.

(d) The obligations under this Section 14 will survive until the expiration of the statute of limitations applicable to the event giving rise to the claim for indemnification.

15. Miscellaneous.

(a) *Governing Law.* This Agreement will be construed in accordance with the laws of Texas without regard for the conflicts of laws and principles thereof.

(b) *Entire Agreement.* This Agreement, and the exhibits attached hereto and incorporated by reference, constitutes the entire agreement between the Parties with the respect to the subject matter hereof and supersedes all prior and contemporaneous oral, written and other agreements between the Parties with respect to the subject matter hereof. This Agreement may only be amended in a writing signed by the Parties.

(c) *Non-Assignment.* Except as otherwise set forth in Section 8, the Parties agree that none of the provisions of this Agreement will be assigned or delegated to any other person or entity; *provided, however,* that Donor

may assign the rights and obligations hereunder to an affiliate or to a purchaser of substantially all of the equity interest in or assets of Donor. In the event Donor assigns its rights and obligations in this Agreement, Donor will notify the Foundation in writing within ten (10) days of said assignment, and the Foundation will have the right to terminate this Agreement upon thirty (30) days of receipt of such notice.

(d) *Notices.* All notices or other communications required or permitted hereunder will be in writing and will be delivered personally, by commercial overnight delivery service, by facsimile or sent by certified, registered or express air mail, postage prepaid, and will be deemed given when so delivered personally, by overnight delivery service or by facsimile, or if mailed, five (5) days after the date of mailing, addressed as follows:

If to Donor: Legal Department
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

If to the Foundation: Michael Banigan, President
6900 Dallas North Parkway
Suite 200
Plano, TX 75024

(e) *Severability.* In the event any portion of this Agreement (or any future amendments) will be held illegal, void or ineffective, the remaining portions of this Agreement will remain in full force and effect. If any of the terms or conditions of this Agreement are in conflict with any applicable Law, then such terms or conditions will be deemed inoperative to the extent that they may conflict therewith and will be deemed to be modified to conform with such Law.

(f) *Waiver.* No waiver hereunder will be valid unless set forth in a writing signed by the Party to be bound thereby. No waiver by either Party of any default, misrepresentation or breach of warranty or covenant hereunder, whether intentional or not, may be deemed to extend to any prior or subsequent default, misrepresentation or breach of warranty or covenant hereunder or affect in any way any rights arising because of any prior or subsequent such occurrence. Neither the failure nor any delay on the part of either Party to exercise any right or remedy under this Agreement will operate as a waiver thereof, nor will any single or partial exercise of any right or remedy preclude any other or further exercise of the same or of any other right or remedy.

(g) *Force Majeure.* The Parties will be excused from performing their obligations under this Agreement if its performance is delayed or prevented by any event beyond such Party's reasonable control, including, but not limited to, acts of God, fire, strike, accidents, explosion, weather, disease, war, insurrection, civil strife, riots, government action or power failure; *provided,* that such performance will be excused only to the extent of and during such *force majeure*.

(h) *Limitation of Liability.* In no event will either party's liability under this Agreement exceed the annual amount of any Donation made by Donor in support of the Program. SUBJECT TO THE TERMS OF SECTIONS 14(a) and (b), UNDER NO CIRCUMSTANCES WILL EITHER PARTY BE ENTITLED TO INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES ARISING IN CONNECTION WITH ANY DEFAULT OR BREACH OF SAID PARTY'S OBLIGATIONS UNDER THIS AGREEMENT OR ANY ATTACHMENTS HERETO.

(i) *Captions and Headings.* The captions and headings in this Agreement are for convenience and reference only, and they will in no way be held to explain, modify or construe the meaning of the terms in this Agreement.

(j) *Counterparts.* This Agreement may be executed in multiple counterparts, each of which is deemed an original, but all of which taken together will constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Chronic Disease Fund, Inc.

By: 
Name: Michael Bantian
Title: President

Date: 11/21/11

Regeneron Pharmaceuticals, Inc.

By: 

Print Name: Beth F. Levine

Title: VP, Assistant General Counsel and Chief Compliance Officer

Date: 11/18/11

Exhibit A

Addendum for Additional Donation

This Addendum for Additional Donation ("Addendum") is made and entered into as of the _____ day of _____, 20__ ("Effective Date of the Addendum"), by and between _____, a non-profit corporation ("Foundation"), and _____ ("Donor").

WHEREAS, Foundation and Donor are the only parties to that certain Donation Agreement dated _____ ("Agreement") pursuant to which Donor has agreed to provide financial support for the Program for treating patients with _____ in accordance with the terms and conditions of the Agreement;

WHEREAS, Donor desires to provide to Foundation, and Foundation desires to receive from the Donor during the Term an additional donation in the amount of _____ Dollars (\$____,000) (the "Additional Donation");

WHEREAS, Donor and Foundation desire to enter into this Addendum to memorialize (i) the parties' agreement that Donor shall provide to Foundation the Additional Donation for the Program during the Term, and (ii) the timing of Donor's payment of such Additional Donation to Foundation; and

WHEREAS, capitalized terms used herein and not otherwise defined shall have the meanings set forth in the Agreement;

NOW THEREFORE, in consideration of the agreements and obligations set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. **Payment and Timing of Additional Donation.** Donor shall provide to Foundation during the Term the Additional Donation for the Program, and such Additional Donation shall be paid by Donor to Foundation within fifteen (15) days following the Effective Date of the Addendum.
2. **Treatment of Additional Donation.** The Additional Donation shall be deemed to be and treated as a "Donation" provided pursuant to the Agreement, and shall be governed by, and subject to, all of the terms and conditions of the Agreement.
3. **Remaining Provisions.** Except as specifically modified in this Addendum, all other provisions of the Agreement shall remain unchanged and in full force and effect.
4. **Modification, Waiver.** No modification or waiver of any provision of this Addendum shall be valid unless it is in writing and signed by the party against whom it is sought to be enforced. No waiver at any time of any provision of this Addendum shall be deemed a waiver of any provision of this Addendum at that time or a waiver of that or any other provision at any other time.
5. **Effective Date.** The modifications set forth in this Addendum shall be effective as of the Effective Date.

IN WITNESS WHEREOF, the parties hereto have caused this Addendum to be duly executed as of the Effective Date.

Chronic Disease Fund

By _____
Name: Michael Banigan
Title: President

Donor:

By _____
Name: Beth F. Levine
Title: VP, Assistant General Counsel and Chief Compliance Officer

Exhibit B
PROGRAM AUDIT PARAMETERS

1. **Program Audit.** For each year of the Agreement, the Foundation will engage an independent review organization ("IRO") to conduct a program audit (the "Program Audit") to assess and evaluate the Foundation's systems, processes, policies and practices related to the Program.
2. **Frequency and Timing of Program Audit.** The Program Audit will occur annually at the direction of the Board, provided that the Program Audit will be conducted only during the normal business hours of the Foundation and in a manner not to be disruptive to the Foundation's day-to-day business activities.
3. **Audit by Independent Review Organization.** The IRO will have expertise in non-profit organizations and in federal and state fraud and abuse laws, including the Anti-Kickback Statute and the Civil Monetary Penalties Law. The Foundation will inform Donor of its selection of an IRO no later than ten (10) days after the commencement of the Program Audit.
4. **Scope of Program Audit.** The Program Audit will address and analyze the Foundation's systems, processes, policies and practices relating to administration of the Program. The review will examine the Program and the Foundation's compliance with the requirements of this Agreement and the following criteria:
 - (a) The Foundation is a *bona fide*, non-profit organization that serves the interests of patients with particular diseases or conditions.
 - (b) The Foundation is independent of any donor to the Program, including Donor (collectively, the "Program Donors"). For purposes of determining independence, no members of the Foundation's governing body will be employed by a Program Donor.
 - (c) The Program receives referrals from a number of sources, including physicians, suppliers, patient advocacy groups, other relevant third party organizations and Program Donors (e.g., through Program Donors' patient assistance programs).
 - (d) The Foundation's determination of whether to provide assistance does not consider the source that referred the patient to the Program.
 - (e) The Foundation bases all financial eligibility determinations on its own established criteria and does not take into account the identity of a provider, supplier or treatment that the patient may use or the identity of a Program Donor whose services or products are used by the applicant.
 - (f) Assistance is available to financially needy beneficiaries who meet the Foundation's income and/or asset criteria, for a period of up to one (1) year, after which each beneficiary's eligibility is reevaluated.
 - (g) Patient requests for assistance under the Program are reviewed on a first-come, first-served basis to the extent funding is available.
 - (h) The Foundation informs patients that they are free to change providers, suppliers or treatments at any time and will not lose their assistance as a result (unless they become ineligible for other reasons).
 - (i) The Foundation does not refer patients to, or recommend, a particular provider, supplier or product.
 - (j) The Foundation does not inform patients of the identities of Program Donors.
 - (k) To the extent feasible, the Foundation furnishes assistance under the Program to the provider, supplier or insurer on behalf of the patient, and where assistance is furnished directly to the patient, the Foundation obtains proof from the patient that the assistance is to satisfy qualifying expenses.
 - (l) The Foundation has a process to solicit donations for the Program from a multitude of sources.
 - (m) The Foundation uses commercially reasonable efforts to publicize the availability of the Program to patient advocacy organizations, other relevant third parties and patients, consistent with the requirements of Section 10 of this Agreement.
5. **Program Audit Report.** The IRO will issue a written report (the "Program Audit Report") to the Foundation, based on its review, with a copy to Donor, addressing the following issues:
 - (a) The Foundation's compliance with this Agreement;
 - (b) The Foundation's compliance with federal and state fraud and abuse laws, including, but not limited to, the Anti-Kickback Statute and the Civil Monetary Penalties Law; and
 - (c) The Foundation's compliance with the terms and conditions set forth in pertinent OIG Advisory Opinions (including but not limited to OIG Advisory Opinion 02-1) or guidance.
6. **Patient and Program Information.** Notwithstanding the foregoing, the Program Audit Report will not include or disclose: (1) any individually identifiable health information (as defined at 45 CFR § 164.103) about any patient of the Program; or (2) other information protected from disclosure pursuant to a confidentiality or similar agreement executed between the Foundation and a donor (including Donor) to a Foundation program (including the Program).